REMARKS

This application has been amended so as to place it in condition for allowance at the time of the next Official Action.

The Official Action maintains the restriction requirement made in the prior Action, thus making the same final, removing claims 8-32 from consideration.

The Official Action objects to the Abstract of the Disclosure. Responsively, the Abstract has been amended as to form.

The Official Action rejects claims 1 and 3-7 under 35 USC 102(e) as being anticipated by TARARA et al. 6,565,885. Reconsideration and withdrawal of this rejection are respectfully requested for the following reasons:

With respect to claim 1, the Office action takes the position that TARARA et al. discloses an electro-dose constituting a medical powder intended for use in a dry powder inhaler.

Applicant respectfully notes that TARARA et al. use neither of the terms "electro-dose" or "electro-powder." The present application uses the term "electro-powder" in describing and claiming the present invention to summarize the properties of a metered medicament dose, formed from a so-called electro-powder having particular electric properties. As taught by the Applicant's U.S. Patent No. 6,696,090 the electro-powder

constituting the metered electro-dose may be chosen from any finely divided medicament powder meeting certain criteria. Significantly, these do not include microstructures as taught by TARARA et al. In fact, the microstructures taught by TARARA et al. are the result from a special spray drying method. The present invention, however, focuses on methods of preparing metered doses of dry, finely divided powders presenting suitable properties for inhalation. Such powders may be produced in any way known in prior art, such as milling, micronizing, and conventional spray drying.

The objective of TARARA et al.'s invention is to present "formulations and methods for the production of perforated microstructures which comprise an active agent" (column 1, lines 17-19) suitable for "both typical and systemic delivery via pulmonary or nasal routes" (column 1, lines 23-24). TARARA et al. go on to teach that "the present invention provides for the formation and use of perforated microstructures and delivery systems comprising such powders" (column 3, lines 46-48). TARARA et al. also disclose that "unlike prior art powders or dispersions for drug delivery, the present invention preferably employs novel techniques to reduce attractive forces between the particles. As such, the disclosed powders exhibit improved flowability and dispersibility" (column 3, lines 50-55).

The present invention is related to electrostatic dosing and "a method for preparation of a metered electro-dose for inhalation" (page 1, lines 4-5). The present invention is silent regarding which prior art method is used for producing a finely divided powder, as this is irrelevant. However, the powder must meet certain criteria (page 7, lines 6-22) to qualify as an electro-powder, which can be used in the process of preparing an electro-dose according to the disclosed method.

TARARA et al. teach that based on measurements using an Anderson cascade impactor, the formulations of the invention will have a fine particle fraction of more than 20% by weight and preferably as much as 80% or more. (See column 27, lines 51-64). Of course, a high fraction of fine particles is an important objective for all formulations and inhalation devices on the market, and the problem is addressed in different ways in prior art. The present invention is a novel contribution in this respect, but it has no dependency or connection to the teachings of TARARA et al.

In TARARA et al., column 22, lines 65-67, column 23, lines 1-22 and column 28, lines 55-57, TARARA et al. discuss which geometric particle sizes of the perforated microstructures are suitable, according to the invention. A preferred mean geometric diameter of the perforated microstructures is between 1 μm and 5 μm. TARARA et al. conclude in column 27, lines 19-39

that a preferred aerodynamic particle diameter is less than 5 μm, which coincides with the established prior art fact that particles having aerodynamic diameters between 1 and 5 μm have the best chance of reaching deep into the lung upon inhalation. Therefore, prior art methods and devices try to keep the delivered particles in the range 1 and 5 μm. The present invention does just that, but in a novel way. It has nothing in common with TARARA et al.'s disclosure, except the objective of delivering a high fine particle fraction.

Further, TARARA et al. discuss in column 23, lines 35-46 the mean porosity of the perforated microstructures. The definition of particle porosity used by TARARA et al. is "the percentage of the particle surface area that is open to the interior and/or a central void." The present invention uses a totally different definition of dose porosity to describe the electro-dose. Here the definition of porosity is "$Dp_{electro\text{-}dose} = 100 - 100(density_{electro\text{-}dose}/density_{electro\text{-}powder})$." This is a relevant measure to describe how electrostatically dosed particles may spread out in relation to one another, i.e., how thinly the particles are deposited in the electro-dose. The present invention achieves the goal of a highly aerosolizable dose with a high fine particle fraction in a totally different way from that of TARARA et al.

The Office action states that claims 3, 4, 6 and 7 include recitations directed to different processes resulting in a porosity of the electro-dose between 75 and 99.9%, which processes are not considered when analyzing the patentability of a product claim. However, irrespective of the recitations characterized as process steps, it should nevertheless be clear that TARARA et al. only disclose ranges of particle porosity, not dose porosity, and the two are entirely distinct from one another. Therefore, the TARARA et al. patent does not anticipate the present invention. Further, it would not be obvious to a person skilled in the art to arrive at the present invention after having studied TARARA et al.

Please note that applicant has amended each of claims 3, 4, 6, and 7 to clarify the language therein.

The Examiner points out that TARARA et al. teach a metered electro-dose having a height of less than 800 μm, which is construed as anticipating claim 5 of the present invention. Apart from the fact that TARARA et al. provide no disclosure regarding "electro-dose" as pointed out above, applicant's careful review of the TARARA et al. patent has identified no mention of the height of a metered dose. Since the metered electro-dose of the present invention is formed by electro-powder particles, and not characterized by being microstructures, the

electro-dose is believed to be quite different from the doses taught by TARARA et al.

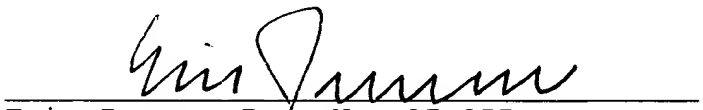
In view of the above, applicant believes that the present application is in condition for allowance and an early indication of the same is respectfully requested.

Should there be any formal matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. §1.16 or under 37 C.F.R.§1.17.

Respectfully submitted,

YOUNG & THOMPSON



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APPENDIX:

The Appendix includes the following item:

- amended Abstract of the Disclosure

ABSTRACT OF THE DISCLOSURE

An electro-dose ~~and a method and a process for obtaining an electro-dose are disclosed. The electro-dose~~ constitutes a metered medical powder and is formed from an electro-powder constituting an active powder substance or a dry powder medical formulation being transferred onto a device member forming a dose carrier. The electro-dose prepared from an electro-powder presents a fine particle fraction (FPF) having of the order 50 % or more of its content with a particle size between 0.5-5 μm. The electro-powder of such a metered electro-dose further provides electrostatic properties regarding absolute specific charge per mass after charging of the order 0.1 to 25 μC/g and presents a charge decay rate constant Q_{50} of more than 0.1 sec with a tap density of less than 0.8 g/ml and a water activity a_w of less than 0.5. The electro-dose porosity is adjusted ~~by means of mechanical and/or electrical vibration of the dose receiving device member during the electro-dose build-up operation~~ to obtain an optimized porosity value in percent of 75 to 99.9 calculated as $100 - 100 \times (\text{Density}_{\text{electro-dose}}/\text{Density}_{\text{electro-powder}})$. ~~The method and the processing of electro-doses is partly illustrated by a flow-chart in which steps 220 to 270 present parameters necessary to be kept under strict control.~~